

CLAIMS

1. Hole forming apparatus for forming a hole in a blood vessel, comprising:
a penetration shaft, having a tip adapted to be inserted through a wall of a blood
5 vessel;
a tissue holder, configured to hold a portion of said wall, said holder being
activated to perform said holding separately from an insertion of said penetration shaft
through said wall; and
a cutting surface adapted to cut through the wall.
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2. Hole forming apparatus according to claim 1, wherein said tissue holder comprises
a rigid barb.
3. Hole forming apparatus according to claim 1, wherein said tissue holder comprises
15 a flexible barb.
4. Hole forming apparatus according to claim 1, wherein said tissue holder comprises
a disk.
- 20 5. Hole forming apparatus according to claim 1, wherein the tissue holder comprises
a hollow tube surrounding the penetration shaft.
6. Apparatus according to claim 5, wherein said hollow tube is configured to be
advanced along said penetration shaft such that said tip is wholly contained by said hollow
25 tube.
7. Apparatus according to claim 6, wherein said hollow tube is long enough to
contain said tip at least until said wall is cut through by said cutting surface.
- 30 8. Hole forming apparatus according to claim 1, wherein the penetration shaft at least
partially encloses said tissue holder.

9. Hole forming apparatus according to claim 8, wherein said tissue holder comprises at least one flexible tissue holding element and wherein the penetration shaft comprises at least one slot wide enough to receive said flexible element therethrough and wherein said tissue holder and said penetration shaft are configured for selectively positioning said penetration shaft relative to said tissue holder such that said tissue holding element and said slot align.
10. Hole forming apparatus according to claim 9, wherein said tissue holder and said penetration shaft are configured such that said tissue holding element is axially displaced from said slot.
11. Hole forming apparatus according to claim 9, wherein said tissue holder and said penetration shaft are configured such that said tissue holding element is angularly displaced from said slot.
12. Hole forming apparatus according to claim 1, wherein said tissue holder lies alongside said penetration shaft.
13. Hole forming apparatus according to claim 1, wherein said tissue holder is mounted on said penetration shaft and comprising a holder releaser configured to selectively release said holder to hold tissue.
14. Hole forming apparatus according to claim 13, wherein said holder releaser comprises a hollow shaft which at least partially encloses said penetration shaft.
15. Hole forming apparatus according to claim 13, wherein the holder releaser lies alongside said penetration shaft.
16. Hole forming apparatus according to claim 13, wherein said holder releaser covers said tissue holder during said insertion of said penetration shaft into said wall.

17. Hole forming apparatus according to claim 16, wherein said holder releaser resiliently compresses said tissue holder during said insertion of said penetration shaft into said wall.
- 5 18. Hole forming apparatus according to claim 1, wherein said tissue holder is configured to be advanced along said penetration shaft after said insertion.
19. Apparatus according to claim 1, wherein said tissue holder is configured to be axially moved relative to said penetration shaft, thereby activating said tissue holder.
- 10 20. Apparatus according to claim 1, wherein said tissue holder is configured to be rotated relative to said penetration shaft, thereby activating said tissue holder.
21. Apparatus according to any of claims 1-20, wherein said tissue holder is
15 configured to retract relative to said cutting surface during said hole forming.
22. Apparatus according to claim 21, wherein said tissue holder is spring loaded to retract.
- 20 23. Apparatus according to claim 21, wherein said retraction is mechanically coupled to a rotation of said cutting surface.
24. Apparatus according to any of claim 1-20, wherein said penetration shaft has a fixed axial position relative to said cutting surface at least after said insertion.
- 25 25. Apparatus according to any of claim 1-20, wherein said penetration shaft is axially retractable relative to said cutting surface.
26. Apparatus according to any of claim 1-20, wherein said cutting surface is
30 configured to cut by rotation.
27. Apparatus according to claim 26, wherein said cutting surface is not rotationally fixed to said tissue holder.

28. Apparatus according to any of claim 1-20, wherein said cutting surface is configured to cut by from an opposite side of said wall from said penetration tip.
- 5 29. Apparatus according to any of claim 1-20, wherein said cutting surface is configured to cut by from a same side of said wall from said penetration tip.
30. Apparatus according to any of claim 1-20, wherein said penetration tip is configured to enter said wall from an outside of said vessel.
- 10 31. Apparatus according to any of claim 1-20, wherein said tissue holder engages a wall of said vessel.
32. Apparatus according to any of claim 1-20, wherein said tissue holder contacts a
15 wall of said vessel at a stop location and thereby prevents relative motion of said wall in a direction of said stop location.
33. Hole forming apparatus for forming an opening in a blood vessel, comprising:
a penetration shaft, having a tip adapted to be inserted through a wall of a blood
20 vessel;
a cutting surface adapted to cut through the wall and having a fixed axial position relative to said penetration shaft tip; and
a tip protector, axially movable to protect the tip of the penetration shaft from
damaging the blood vessel after the penetration shaft is inserted through the wall of the
25 blood vessel.
34. Hole forming apparatus according to claim 33, wherein said tip protector comprises at least one tissue holding element configured to hold at least a portion of said wall after said insertion.
- 30 35. Apparatus according to claim 34, wherein said tip protector has a length, distal of said tissue holder, greater than an axial distance between said tip and said cutting surface.

36. Apparatus according to any of claims 33-35, wherein the tip protector comprises a hollow tube which surrounds the penetration shaft.
- 5 37. Hole forming apparatus for forming a hole in a blood vessel, comprising:
a slit-forming penetration head having a tip on a distal end thereof and configured to be inserted into, and form a slit, in a blood vessel wall; and
a cutting surface not-contiguous with said tip, configured to cut said wall such that said cut and said slit link to provide a boundary cut of said wall, defining said hole.
- 10 38. Apparatus according to claim 37, wherein said cutting surface is formed on a proximal side of said head.
39. Apparatus according to claim 37, wherein said tip is asymmetrically located on
15 said head relative to an axis of said apparatus.
40. Hole forming apparatus according to claim 37, wherein the penetration head is solid.
- 20 41. Hole forming apparatus according to claim 37, wherein the penetration head is hollow.
42. Apparatus according to claim 41, and including at least one head tissue holder positioned inside said head and configured to prevent a cut out portion of the wall of the
25 blood vessel from passing through said head in a direction of said tip.
43. Apparatus according to claim 42, wherein said tissue holder is fixed to said head.
44. Apparatus according to claim 42, wherein said tissue holder comprises a hook.
- 30 45. Apparatus according to claim 42, wherein said penetration head has an arcuate profile when viewed along its axis.

46. Hole forming apparatus according to claim 37, and including a sharpened tip at a proximal end of the penetration head.
- 5 47. Hole forming apparatus according to claim 46, wherein said sharpened tip is on a same plane as said penetration tip and an axis of said penetration head.
48. Hole forming apparatus according to claim 37, and including an anchor comprising a member defining a trans-axial slot, said slot having a width sufficient to receive a
10 thickness of said wall.
49. Hole forming apparatus according to claim 48, wherein said member comprises a tube defining a lumen having a diameter sufficient to enclose said penetration head.
- 15 50. Hole forming apparatus according to claim 48, wherein said member only partly surrounds said penetration head.
51. Hole forming apparatus according to any of claims 48-50, and including an anchor tissue holder attached to said anchor, which anchor tissue holder prevents a cut out portion
20 of the wall of the blood vessel from passing into the blood vessel.
52. Hole forming apparatus according to any of claims 48-50, wherein said member has a distal end.
- 25 53. Apparatus according to claim 52, wherein said distal end comprises an anchor cutting surface.
54. Apparatus according to claim 52, wherein said distal end comprises said cutting surface.
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55. Apparatus according to claim 52, wherein said distal end and a proximal end of said penetration head cooperate to provide a scissors cutting action.

56. Apparatus according to claim 52, wherein said distal end and a proximal end of said penetration head cooperate to provide an anvil cutting action.
- 5 57. Hole forming apparatus for forming a hole in a blood vessel, comprising:
a penetration head adapted to penetrate a blood vessel wall;
a slotted anchor, defining a trans-axial slot having a width sufficient to receive a thickness of said wall; and
a cutting surface configured to cut said wall while said wall is held by said slotted
10 anchor.
58. Apparatus according to claim 57, wherein said anchor comprises a trans-axially-slotted tube.
- 15 59. Hole forming apparatus according to claim 57, wherein the penetration head comprises a distal portion of the anchor.
60. Hole forming apparatus according to any of claims 57-59, and including a tissue holder which prevents a cut out portion of the wall of the blood vessel from passing into
20 the blood vessel.
61. Apparatus according to claim 57, wherein said cutting surface is formed on a proximal side of said penetration head.
- 25 62. Hole forming apparatus for forming a hole in a blood vessel, comprising:
a penetration head having a tip adapted to penetrate a blood vessel wall and defining an axial lumen; and
a tip protector configured to pass through said lumen and protect said tip from damaging the blood vessel after said penetration.
- 30 63. Apparatus according to claim 62, wherein said tip protector comprises a folded tab defining a receptacle configured to receive said tip therein.

64. Apparatus according to claim 63, wherein said tab is resiliently distorted during passage through said lumen.
- 5 65. Apparatus according to claim 62, wherein said tip protector has a fixed axial location relative to said apparatus such that retraction of said penetration head causes said tip protector to pass through said lumen and protect said tip.
66. Apparatus according to claim 62, wherein said tip protector comprises a control for
10 manually positioning said tip protector to selectively protect said tip.
67. Hole forming apparatus for forming a hole in a blood vessel, comprising:
a tissue holder configured to be inserted through a blood vessel wall;
a base configured to be positioning on an opposite side of said wall; and
15 a display coupled to said tissue holder and said base and configured to show an indication based on a relative distance between said tissue holder and said base.
68. Apparatus according to claim 67, wherein said tissue holder includes at least one tissue retraction prevention element which prevents retraction of said tissue holder back
20 through said wall.
69. Apparatus according to claim 67, wherein said display is mechanically coupled to said holder and said base.
- 25 70. Apparatus according to claim 67, wherein said base contacts said wall with a blood vessel wall cutting surface.
71. Apparatus according to claim 67, comprising a spring which retracts said holder relative to said base.
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72. Apparatus according to any of claims 67-71, wherein said display converts said distance into a measure of compressibility of said wall.

73. Apparatus according to any of claims 67-71, wherein said display converts said distance into a measure of a thickness of said wall.
- 5 74. Hole forming apparatus for forming a hole in a blood vessel, comprising:
a penetration head mounted on a shaft and adapted to penetrate a blood vessel wall; and
a tissue receptacle configured to receive said wall after said penetration,
wherein said shaft is not co-axial with said tissue receptacle.
- 10 75. Apparatus according to claim 74, wherein said shaft is outside of said tissue receptacle.
76. Hole forming apparatus for forming a hole in a blood vessel, comprising:
15 a plurality of helical coils adapted to penetrate and engage a blood vessel wall; and
a base defining a cutting surface for cutting said wall and configured to be axially moved relative to said helical coils.
77. Apparatus according to claim 76, wherein said coils include at least two coils
20 having opposite helicity.
78. Apparatus according to claim 76, wherein said coils include at least two coaxial coils.
- 25 79. Apparatus according to claim 76, wherein said coils include at least two non-coaxial coils.
80. A method of forming a hole in the wall of a vessel, comprising:
providing a hole former comprising a shaft having a penetrating tip formed at a
30 distal end of the shaft, an outer shaft disposed about the shaft and configured to be slideable with respect to the shaft, the outer shaft having at least one projecting element, and a base disposed about the outer shaft having a cutting lip, the base configured to be slideable relative to the outer shaft;

penetrating a vessel wall with the penetrating tip to form an opening;
passing the outer shaft and the at least one projecting element through the opening;
and

5 cutting the vessel wall with the cutting lip of the base to form a hole in the wall of
the vessel.

81. A method according to claim 80, comprising retracting the outer shaft such that the
at least one projecting element contacts the inner surface of the vessel wall prior to said
cutting.

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82. The method of claim 80, wherein the shaft and the base are fixed relative to one
another.

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83. The method of claim 80, wherein the shaft is moveable independently of the base.

84. The method of claim 83, wherein the penetrating tip is retracted into the outer shaft
one the outer shaft has passed through the opening.

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85. The method of claim 80 or 84, wherein the outer shaft shields the inner surface of
the vessel wall from the penetrating tip during the cutting step.

86. The method of claim 80, wherein the base is rotated to cut the hole in the vessel
wall.